UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,564	12/18/2001	Rasmus Jansson	45687-00082USPT	8348

23932 7590 06/02/2004

JENKENS & GILCHRIST, PC
1445 ROSS AVENUE
SUITE 3200
DALLAS, TX 75202

EXAMINER	
SODERQUIST, ARLEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,564	JANSSON ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4-6-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 20-25 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 20 it is not clear if the fluids are limited to blood or another body fluid or simply a urea containing fluid since the "such as" language does not appear to limit the type of fluid to those listed. As a result the limitation is being treated as a urea containing fluid for examination purposes. In claim 23 it is not clear if the period is defined as each pulse in the pulse train or as a point that the pulses start to repeat in the sequence. For examination purposes the limitation is being treated as the time from the start of the pulse sequence to the point at which the pulse sequence starts to repeat itself. In claim 24 it appears that a plurality of working electrodes is required and the pulse program is specific to each working electrode since it is difficult if not impossible to have a different pulse program applied to each of the working and counter electrodes as defined in claim 20. In claim 25 it is not clear if successive pulses are required to change sign from positive to negative or negative to positive or if only the first pulse is so required. In claim 30 it is not clear what further structural limitation is provided since there is no specific structural limitation presented to distinguish a sample being blood or any other type of sample as there is in claim 31.

2. Claims 26-27 and 30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Winquist (Analytic Chimica Acta 1997, hereinafter referred to as Winquist'97).

3. Claims 1, 4-7, 9-11, 14 and 116-17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Winquist (Measurement Science and Technology 1998, hereinafter referred to as Winquist'98). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 20-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winquist (Analytic Chimica Acta 1997, hereinafter referred to as Winquist'97 or Measurement Science and Technology 1998, hereinafter referred to as Winquist'98 in view of Bouzid, Locatelli (full article newly cited) and Senda (newly cited and applied).

In the paper Winquist'97 teaches an electronic tongue based on voltammetry. Presently, great interest is shown in the concept of an electronic nose. It consists of an array of gas sensors with different selectivity patterns, a signal collecting unit and pattern recognition software applied to a computer. Similar concepts, but for analysis in liquids have also been described, and since they are related to the tasting sense, the term 'electronic tongue' or 'taste sensor' was coined. This paper describes how various voltammetric techniques such as large and small amplitude pulse voltammetry (LAPV and SAPV) can generate information when combined with a multivariate analysis method. A prototype of an electronic tongue was designed, based on the combination of voltammetry, using a double working electrode of gold and platinum, and principal component analysis. It is demonstrated how this electronic tongue is able to classify various samples such as fruit juices, still drinks and milk. It was also possible to follow aging processes of milk and orange juice when stored at room temperature. Winquist'97 does not teach the method and apparatus applied to urea containing liquid samples.

In the paper Winquist'98 monitors the freshness of milk by an electronic tongue on the basis of voltammetry. They describe an electronic tongue which consists of a reference electrode, an auxiliary electrode and five wires of different metals (gold, iridium, palladium, platinum and rhodium) as working electrodes. The measurement principle is based on pulsed voltammetry, in which successive voltage pulses of gradually changing amplitudes are applied to the working electrodes connected in a standard three-electrode configuration. The five working electrodes were successively connected and corresponding current-response transients are recorded. The electronic tongue was used to follow the deterioration of the quality of milk due to microbial growth when milk is stored at room temperature. The data obtained were treated with principal component analysis and the deterioration process could clearly be followed in the

diagrams. To make models for predictions, projections to latent structure and artificial neural networks were used. When they had been trained, both models could satisfactorily predict the course of bacterial growth in the milk samples. Winquist'98 does not teach the method and apparatus applied to urea containing liquid samples.

In the paper Bouzid teaches flow-injection methods for the determination of 18 and related compounds uracil derivatives with voltammetric detection by means of differential-pulse amperometry (DPA) or differential-pulse cathodic stripping voltammetry (DPCSV). The carrier stream is a borax/KNO_3/HNO_3 (or NaOH) solution containing 0.001 vol. % Triton X 100. This surfactant displaces the oxygen reduction. peak to such negative potentials that deaeration is unnecessary for detection of compounds having peak potentials in the range 180-70 mV (vs. Ag/AgCl) at pH 7.6. At the hanging mercury drop electrode, the uracil derivative is deposited from the flowing sample at a fixed potential more positive than the relevant peak potential and stripped under stopped-flow or slow-flow conditions. In the amperometric mode, a constant potential also more positive than the relevant peak potential is applied to the dropping mercury electrode and the resulting peak is measured under flow conditions. Linear calibration graphs were found for most of the compounds at 10^{-7}-10^{-6} M by DPA and about one order of magnitude lower by DPCSV. The limit of determination for 5-iodouracil was 5×10^{-9}M (~1.2 ng/mL). Separation is needed for applications to blood or urine. Samples deproteination followed by high-performance liquid chromatography with a reversed-phase column proved satisfactory. Separations of various uracil derivatives, and of 5-fluorouracil, uric acid and 5-fluorodeoxyuridine, are described; spectrophotometric and amperometric detectors were used sequentially to check performance.

In the abstract Locatelli teaches the determination of chromium(VI) in dialysis fluids by alternating current and differential pulse voltammetry. A.c. and differential pulse voltammetry are employed for the determination of Cr(VI) in dialysis fluids, using 0.1 mol/L dibasic ammonium citrate as supporting electrolyte (pH 5.9). A 3-electrode cell was used. The working electrode was a long-lasting sessile-drop Hg electrode with a drop time of 240-300 s. Precision (expressed as relative standard deviation - s_r%) and accuracy (expressed as relative recovery - R%) were also reported.

In the paper Senda describes work on amperometric ion sensors and their applications in

food chemistry and clinical chemistry. Amperometric ion sensors based on amperometry or voltammetry with a polarizable oil/water interface are described and discussed for their applicability in analysis of foods and body fluids. The amperometric sensor gives a current response proportional to the concentration of the analyte. The pulsed amperometric technique is used to follow the current response of the sensors, which allows the sensors high reproducibility and long lifetime. In amperometry or voltammetry, simultaneous determination of two or more analytes with a single sensor can be achieved. Also, correction for (residual) current due to interfering (residual) substance(s) is relatively easy. Amperometric sensors for the determination of K and Na ions and of volatile amines (ammonia and trimethylamine) in foods are described. A biosensor for urea and its applicability to body fluid analysis are presented. A creatinine biosensor also is described.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the devices of Winquist'97 or Winquist'98 on the samples of Senda, Bouzid or Locatelli in the body fluids disclosed therein to obtain the measurement advantages of the Winquist'97 or Winquist'98 pulse sequences and multivariate analysis.

5. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The newly cited and applied Senda reference clearly teaches the application of electrode sensors to the measurement of urea in body fluids.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to analysis of urea samples with electrode sensors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose current telephone number is (571) 272-1265 as a result of the examiner moving to the new USPTO location. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Arlen Soderquist

June 1, 2004

ARLEN SODERQUIST
PRIMARY EXAMINER